K070438

OCT 17 2007

SECTION 2.0 - 510(k) SUMMARY

In accordance with the requirements of 21 CFR 807.92, this 510(k) Summary is provided:

Submitter: Medtronic MiniMed
18000 Devonshire St.
Northridge, CA 91325

Contact: Jodie Rogers, (818) 576-5708

Date: February 13, 2007

Name of Device: Medtronic MiniMed CareLink™ USB Connector, Model MMT-7305

Predicate Device: Com-Link Communication System, Model MMT-7304

Description of the Device: The Medtronic MiniMed CareLink USB Connector is an accessory device that facilitates wireless communication between compatible Medtronic MiniMed radiofrequency telemetry devices and a personal computer.

The hardware component of the CareLink USB Connector consists of a radio-frequency (RF) transceiver enclosed in a plastic housing and one USB connector that is compatible with a type A (female) USB port of a personal computer (PC) or a USB hub. The CareLink USB Connector has a form factor similar to a USB flash memory stick and will by recognized by the PC as a USB device.

The CareLink USB Connector is designed for use with Medtronic MiniMed devices that use Paradigm radiofrequency telemetry. Data is transferred between Medtronic MiniMed Paradigm RF compatible devices and a personal computer (PC) using select Medtronic MiniMed data management software applications.

Intended Use of the Device: The Medtronic CareLink USB Connector is indicated for use by patients at home and clinicians in a medical office setting to facilitate communication between Medtronic diabetes therapy management devices that use Paradigm-compatible RF telemetry and a personal computer that uses data management application software.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device and the lawfully marketed predicate devices provide similar function, and use radiofrequency technology to communicate. The primary difference between the two devices is physical, in that, the new device is designed to connect to the computer's USB port instead of a serial port. These modifications do not affect the safety or effectiveness of the device.

2/13/07

Jodie Rogers
Regulatory Affairs
Medtronic MiniMed

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2007

Ms. Jodie Rogers
Senior Regulatory Affairs Specialist
Medtronic MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

Re: K070438
Trade/Device Name: Medtronic MiniMed CareLink™ USB Connector
(Model: MMT-7305)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: October 4, 2007
Received: October 5, 2007

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070438

Device Name: Medtronic MiniMed CareLink™ USB Connector (Model: MMT-7305)

Indications For Use: The Medtronic CareLink™ USB Connector is indicated for use by patients at home and clinicians in a medical office setting to facilitate communication between Medtronic diabetes therapy management devices that use Paradigm-compatible RF telemetry and a personal computer that uses data management application software.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070438